SENTINEL
DIAGNOSTICS

NOV 17 2005

510k Summary
Sentinel UIBC Liquid

K Number: K051111

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3. Date summary prepared: 10 November 2005

4. Device name and classification

The Sentinel UIBC Liquid described in this 510(k) consists of reagents and standard, packaged and distributed in one kit. The device is intended to be sold as an *in-vitro* test for professional use.

Product name and classification information are provided in Table 4.1 below.

Table 4.1 Device names and classification of Sentinel UIBC Liquid

Trade/Device Name	Regulation Number	Regulation name	Classification panel	Regulatory class	Product Code
Sentinel UIBC Liquid	21 CFR 862.1415	UIBC	Clinical Chemistry	I	JMO

5. Device description

The Sentinel UIBC Liquid described in this 510(k) submission is composed of reagents and standard, packaged and distributed in the same kit. The device is intended to be sold as an in vitro test for professional use.

Serum is added to an alkaline buffer/reductant solution containing a known concentration of iron to saturate the available binding sites on transferrin. The iron that remains free after transferrin saturation is reduced to a ferrous state and then complexed by Ferene-S to form a stable complex, of which the color intensity is measured at 580-600nm. UIBC is therefore determined by subtracting the quantity of unbound iron from the total added quantity.

6. Intended Use

The Sentinel UIBC Liquid (Unsaturated Iron Binding Capacity) assay is intended to measure the unsaturated iron-binding capacity in serum. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. CFR 862.1415

7. Comparison with Predicate Devices

Table 7.1 lists the predicate device for the Sentinel product included in this submission, and provides information on the regulatory status of the predicate device, including the 510(k) number.

Table 7.1 Predicate device for Sentinel UIBC Liquid

Sentinel Trade Device Name	Predicate Device Name	Predicate Device Manufacturer	Predicate device (k)	FDA clear-ance date
Sentinel UIBC Liquid	Roche UIBC	Roche	K770748*	06/01/1977

* The Roche UIBC - Predicate Device – was cleared via Hycel, INC. (K0770748). Roche aquired Hycel on June 8, 1979.

Table 7.2 below report a comparison of the Sentinel UIBC Liquid with the Predicate Device Roche UIBC. No substantial differences can be noted. The two devices are intended to be used on Automatic Analyzers: the predicate device with the Roche/Hitachi analyzers, the Sentinel UIBC Liquid on the Abbott AEROSET and ARCHITECT analyzers.

Table 7.2 Comparison with Predicate Device

#	Design Feature	New Device UIBC Liquid	Predicate Device Roche UIBC
1	Sample Type	Human serum and plasma (only heparin salts)	Same
2	Principle	• Transferrin saturation with a known iron amount; • quantitation of Free iron; • UIBC determined by subtracting the quantity of unbound iron from the total added quantity	Same
3	Chromogen	Ferene-S	FerroZine
4	Calibration	Against aqueous standard	Same
5	Linearity	up to 500 µg/dL	Same
6	Reference Range	110-370 µg/dL	Same
7	Instrumentation	Abbott AEROSET and Abbott ARCHITECT *c*8000 analyzers	Roche / Hitachi Automatic Analyzers

8. Performance Data

Performance evaluations included sensitivity, intra- and inter-assay precision, linearity and method comparison. In the method comparison study evaluating 60 serum samples, the correlation (r, y=mx+q)) of the Sentinel UIBC Liquid on the Abbott AEROSET to the predicate device Roche UIBC was 0.9144, y=1.024x + 14.64.

9. Conclusion

The performance and safety data presented in this premarket notification support a finding of substantial equivalence between the Sentinel UIBC Liquid and the predicate devices specified in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2005

Mr. Davide Spada
Application Specialist
Sentinel CH Srl
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20155 Milan, Italy

Re: k051111
Trade/Device Name: Sentinel UIBC Liquid
Regulation Number: 21 CFR 862.1415
Regulation Name: Iron-binding capacity test system
Regulatory Class: Class I
Product Code: JQF
Dated: October 18, 2005
Received: November 8, 2005

Dear Mr. Spada:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051111

Device Name: Sentinel UIBC Liquid

Indications For Use:

The Sentinel UIBC Liquid (Unsaturated Iron Binding Capacity) assay is intended to measure the unsaturated iron-binding capacity in serum and plasma. Iron-binding capacity measurements are used in the diagnosis and treatment of anemia. CFR 862.1415

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051111